DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed on have been 1/15/2008 has been considered. Initialed copies are enclosed.

Objections

3. Claim 28 is objected for the following reasons: formula is misspelled. Appropriate correction is advised.

Election/Restrictions

4. Applicant's election of Group II claims 22-24 are acknowledged. Examiner considers Applicant's request that Claim 28, 31 and 32 be included in Group II, since these claims depend from Claim 27 part of Group II or depend from a claim dependent from claim 27. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims (42-43) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group IV (claims 42-43), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in reply filed on 1/11/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22-24, 27-28, 31-32, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising tulathromycin and an antigenic agent of Manneheimia (Pasteurella) haemolytica Bacterin-Toxoid (see Example 1) does not provide enablement for a human or non-human vaccine comprising least two components, with the two components administered either concurrently, or co-administered within a month, where the first component is an adjuvant comprising one or more antimicrobial agent and the second component is one or more antigenic agents further comprising formula II and further comprising a mixture of compounds formula I and II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The claims are directed to a human or non-human vaccine comprising least two components, with the two components administered either concurrently, or co-administered within a month, where the first component is an adjuvant comprising one or more antimicrobial agent and the second component is one or more antigenic agents further comprising formula II and further comprising a mixture of compounds formula I and II.

Breadth of the claims: In the instant case, the claims are overly broad. The claims are drawn to a human or non-human vaccine comprising least two components, with the two components administered either concurrently, or co-administered within a month, where the first component is an adjuvant comprising one or more antimicrobial agents and the second component is one or more antigenic agents further comprising formula II and further comprising a mixture of compounds formula I and II, thus not limiting to a particular vaccine. The specification is only limited to non-human vaccine comprising tulathromycin and an antigenic agent M. haemolytica.

The amount of direction or guidance presented:

As discussed above, the specification does not teach of formula I or II in any vaccine composition comprising and adjuvant composition. The specification discloses Tables that are the suggestive use of the formula I and II in vaccine comprising an adjuvant composition, and the speculative use of the formula I and II to treat or prevent any disorder.

The absence or presence of working examples:

The specification does contain working examples, however, none are directed at evidencing or indicating that a human or non-human vaccine comprising formula I and II for any disease or disorder. All the working examples are directed at showing non-human vaccine comprising tulathromycin and an antigenic agent M. haemolytica.

State of the Art, level of predictability and unpredictability, and quantity of experimentation necessary:

As noted above, the claimed invention is directed at vaccine compositions, wherein the claims are only limited to a particular vaccine as set forth supra. In view of

the types of diseases or disorder encompassed by the claims, it should be noted there does not exist an art-recognized cancer, fungal, bacterial and parasitic vaccine comprising an adjuvant composition further comprising formula II and further comprising a mixture of formula I and II. In the instant case, the current literatures only recognize antimicrobial agents that are susceptible Pasteurella haemolytica to treat systemic bacterial diseases in mammals (see US Patent No. 5,929,086). The art indicate a method of preparing 13-membered azalides compounds and pharmaceutically acceptable salts thereof. The art indicate the 13-membered azalides are antibacterial agents that may be used to treat various bacterial and protozoa infections (see US Patent No. 6,329,345). The state of the art does not teach a vaccine comprising formula I and II. The state of the art indicate as set forth by Plotkin et al (VACCINES W.B. Saunders Company, 1988, page 571) "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies… and thus protect the host against attack by the pathogen." This teaching directly addresses whether any agent, wherein said agent provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism. Furthermore, A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Therefore the contemporary knowledge in the art would not allow one skilled in the art to use the instantly claimed invention with a reasonable expectation of success and without undue experimentation.

Therefore, in view of the above enablement analysis, one skilled in the art would not be able to practice the instantly claimed invention with a reasonable expectation of success without an undue burden of experimentation.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F. 2d 1557, 1562,

27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al 1999 Cellular Immunology vol. 197 pgs. 145-150.

Claims 22-23 are drawn to a human or non-human vaccine comprising least two components, with the two components administered either concurrently, or co-administered within a month, where the first component is an adjuvant comprising one or more antimicrobial agent and the second component is one or more antigenic agents.

Sato et al teach a composition comprising one antimicrobial agent (14-member macrolide antibiotic and an antigenic agent unmethylated CpG oligonucleotide in a DNA vaccine (see abstract, 145-150).

As to the recitation “human or non-human vaccine” and “administered either concurrently, or co-administered within a month” is considered intended use and has no structural limitation on the composition.

7. Claims 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Post et al 1991 J. Vet. Diagn. Invest 3 pgs. 124-126.

Claims 22 and 24 are drawn to a human or non-human vaccine comprising least two components, with the two components administered either concurrently, or co-administered within a month, where the first component is an adjuvant comprising one or more antimicrobial agent and the second component is one or more antigenic agents.

Post et al teach antimicrobial susceptibilities of *Pasteurella haemolytica* isolates (one or more antigens M. haemolytica antigen) recovered from cattle with respiratory disease were determined by analyzing for patterns of resistance to ceftiofur. Thus Post et al teach a human or non-human animal vaccine comprising at least two components, with the two components administered either concurrently, or co- administered within a month, where the first component is an adjuvant comprising one antimicrobial agents and the second component is one or more antigenic agents, wherein the vaccine is for non-human animals, where the antimicrobial agent is ceftiofur, and where the antigenic agent is one or more antigens of M. haemolytica antigen.

Regarding the recitations of "a human or non-human animal vaccine" and "administered either concurrently, or co- administered within a month" are considered an intended use and thus is given no patentable weight on the two components. Therefore the claims are drawn to two components, where the first component is an adjuvant comprising one or more antimicrobial agent and the second component is one or more antigenic agents.

Status of the Claims

7. No claims allowed.

Claims 22-24, 27-28, 31-32, and 44 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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